## REMARKS

The Final Office action dated October 5, 2009 is acknowledged. Claims 1 and 4-35 are pending in the instant application. Claims 1, 4-8, 17-19, 21, 34 and 35 have been rejected and claims 9-16, 20 and 22-33 have been withdrawn. Claims 1 and 34 are amended herewith, as discussed below. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

### Rejection of Claims 1, 4-8, 17-19, 21, 34 & 35 Under 35 U.S.C. 103(a)

Claims 1, 4-8, 17-19, 21, 34 & 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0136752 (Whittle, et al.). The Examiner argues that Whittle, et al. disclose the limitations of the presently claimed invention, as discussed in detail on pages 4-7 of the present Final Office action. In particular, the Examiner states that Whittle, et al. teach a film-shaped, pharmaceutical formulation for administration to a mucosal surface, wherein the formulation comprises at least one lipophilic medicament and a matrix which comprises at least one emulsifying agent and a sweetening or flavoring agent. The Examiner refers to Example 9 of Whittle, et al. which, according to the Examiner, expressly teaches a melted mass (i.e., matrix) formulation which serves as a reservoir for two cannabis active ingredients: tetrahydrocannibinol (THC) and cannabidiol (CBD) and that the formulation expressly teaches the presence of a cannabis extract (e.g., THC) and a cannabinoid compound present, each in the amounts of 5 parts per 90 parts (e.g., about 5.5% by weight). The Examiner acknowledges that Whittle, et al. fail to teach the overall administration form as conforming to the instantly claimed thickness limitations.

In this regard, the Examiner concludes that it would have been obvious to one skilled in the art to prepare the instantly claimed single- or multi-layered, cannabis extract/cannabinoid mucoadhesive administration form as taught by Whittle, et al. and to modify the thickness of the cast film form to produce the presently claimed invention. The Examiner further concludes that one skilled in the art would have been highly motivated to do so because Whittle, et al. expressly teach each of the aspects of the presently claimed, with the exception of conforming said article to the claimed dimensions. The Examiner also states that it would have been *prima facie* obvious to one skilled in the art to optimize the thickness parameter of the administration forms for any number of reasons related to the efficacy or aesthetic aspects of the invention (i.e., to be able to accommodate the variety of different oral or buccals locations to which the form will be applied).

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion set forth in the Final Office action. As noted above, the Examiner states that Whittle, et al. teach nearly every limitation of the presently claimed invention, except for the thickness limitations and that Table 2 of Whittle, et al. teaches hydroxypropyl cellulose and propylene glycol alginate would represent species of the genera of "propyl cellulose" and

"alginates."

By the present response, claims 1 and 34 have been amended to delete "hydroxypropyl cellulose," "propyl cellulose," "alginates" and "alginic acid." In this regard, it is also respectfully noted that the Examiner refers to the "water-soluble polymer limitation of claims 3 and 17" at page 5, lines 2-3 of the Final Office action. Claim 3 has been canceled and claim 17 addresses a different limitation.

Regarding the remaining polymers recites in claims 1 and 34, it is respectfully submitted that Whittle, et al. fail to teach or suggest that acacia gum or any other of the polymers listed in Table 2 of Whittle, et al. could be replaced by any of the polymers recited in present claims 1 and 34. Therefore, it is submitted that the reference fails to render the present claims obvious to one skilled in the art and fails to teach every limitation of the present claims.

At page 4, lines 12-14 of the Final Office action, it is also stated that claim 34 "does not further limit claim 1 since cannabis oils, absent a clearer definition, are interpreted in the same scope as cannabis extracts." The Applicant respectfully disagrees since the term "oil" relates to an extract which is in the liquid state, whereas "extract" pertains to either solids or liquid. The Applicant believes that such definitions and meanings would be readily known to one skilled in the relevant art (see, for example, the enclosed Exhibit A).

In view of the above, the teachings of Whittle, et al. fail to make the presently claimed invention obvious. It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and

every element of the present invention recited in the present claims is not set forth in Whittle, et al., nor would one skilled in the art be motivated to modify Whittle, et al. to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

**Conclusion**

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: February 4, 2010

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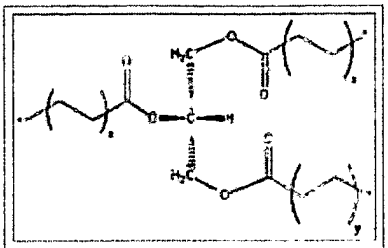
EXHIBIT
4

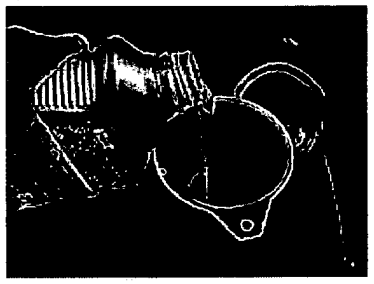
# Oil

From Wikipedia, the free encyclopedia

An **oil** is any substance that is liquid at ambient temperatures and is hydrophobic but soluble in organic solvents. Oils have a high carbon and hydrogen content and are nonpolar substances. The general definition above includes compound classes with otherwise unrelated chemical structures, properties and uses, including vegetable oils, petrochemical oils, and volatile essential oils. All oils can be traced back to organic sources.



General structure of a triglyceride, the main constituent of vegetable oil and animal fats



Synthetic motor oil being poured

## Contents



## Types

### Essential oil

An essential oil is a concentrated, hydrophobic liquid containing volatile aroma compounds from plants. An oil is 'essential' in the sense that it carries a distinctive scent, or essence, of the plant. Essential oils do not, as a group, need to have any specific chemical properties in common, beyond conveying

characteristic fragrances. In history, oil has been used by Vikings, Spartans, etc. in war as they believed it made them stronger.[*citation needed*]

Essential oils are generally extracted by distillation. Other processes include expression, or solvent extraction. They are used in perfumes, cosmetics and bath products, for flavoring food and drink, and for scenting incense and household cleaning products.

### Mineral oil

Mineral oils, found in porous rocks underground, originated from organic material, such as dead plankton, accumulated on the seafloor in geologically ancient times. Through various geochemical processes this material was converted to mineral oil, or petroleum, and its components, such as kerosene, paraffin waxes, gasoline, diesel and such. These are classified as mineral oils because they do not have an organic origin on human timescales, and are instead derived from underground geologic locations, ranging from rocks, to underground traps, to sands.

Other oily substances can also be found in the environment; the most well-known of those is asphalt, occurring naturally underground or, where there are leaks, in tar pits.

Petroleum and other mineral oils (specifically labelled as petrochemicals) have become such a crucial resource to human civilization in modern times they are often referred to by the ubiquitous term of "oil" itself.

### Organic oils

Oils are also produced by plants, animals and other organisms through organic processes, and these oils are remarkable in their diversity. *Oil* is a somewhat vague term in chemistry; instead the scientific term for oils, fats, waxes, cholesterol and other oily substances found in living things and their secretions, is *lipids*.

Lipids, ranging from waxes to steroids, are somewhat hard to characterize, and are united in a group almost solely based on the fact that they all repel, or refuse to dissolve in, water, and are however comfortably miscible in other liquid lipids. They also have a high carbon and hydrogen content, and are considerably lacking in oxygen compared to other organic compounds and minerals.

### Synthetic oils

Synthetic oil is a lubricant consisting of chemical compounds which are artificially made (synthesized) from compounds other than crude oil (petroleum). Synthetic oil is used as a substitute for lubricant refined from petroleum, because it generally provides superior mechanical and chemical properties than those found in traditional mineral oils.

## Applications

## Food

Many edible plant and animal oils and fats are used in cooking and food preparation. In particular, many foods are fried in oil much hotter than boiling water. Oils are also used for flavoring and for modifying the texture of some foods e.g. stir fry.

Health advantages are claimed for a number of specific oils such as omega 3 oils (fish oil, flaxseed oil, etc), evening primrose oil, and olive oil. Trans fats, often produced by hydrogenating vegetable oils, are known to be harmful to health.

A bottle of olive oil used in food.

## Hair

Oil is used on hair to give it a lustrous look. It helps to avoid tangles and roughness to the hair. It also helps the hair to be stabilised and grow faster.[*citation needed*]

## Fuel

*Main article: Petroleum*

Almost all oils burn in aerosol form generating heat, which can be used directly, or converted into other forms of fuels by various means. The oil that is pumped from the ground is then shipped via oil tanker to an oil refinery. There, it is converted from crude oil to diesel fuel (petrodiesel), ethane (and other short-chain alkanes), fuel oils (heaviest of commercial fuels, used in ships/furnaces), gasoline (petrol), jet fuel, kerosene and liquefied petroleum gas.

## Electricity generation

Oil and any of its more refined products are often used to create electricity. This is done by means of a steam engine. The steam engine turns the thermal energy into rotary motion, which can then be transformed into electricity, by means of a generator.

## Heat transport

Many oils have higher boiling points than water and are electrical insulators, making them useful for liquid cooling systems, especially where electricity is used.

## Lubrication

Due to their non-polarity, oils do not easily adhere to other substances. This makes oils useful as lubricants for various engineering purposes. Mineral oils are more suitable than biological oils, which degrade rapidly in most environmental conditions.

### Painting

Color pigments can be easily suspended in oil, making it suitable as supporting medium for paints. The slow drying process and miscibility of oil facilitates a realistic style. This method has been used since the 15th century.

### Petrochemicals

*Main article: Petrochemicals*

Crude oil can be processed into petroleum; 'petrochemicals' are chemical products made from raw materials of petroleum or other hydrocarbon origin. They are used in products such as detergents, fertilizers, medicines, paints, plastics, synthetic fibres, and synthetic rubber.

## Other uses

Sulfuric acid has been called oil of vitriol in pre-scientific times, due to its viscous consistency. Even in modern times, it is sometimes called vitriolic acid, and caustic personalities are called "vitriolic". [*citation needed*] Sulfuric acid is not a petrochemical, and in modern parlance, is not an oil.[*citation needed*]

### Religion

Oils have been used throughout history as a fragrant or religious medium. Oil is often seen as a spiritually purifying agent. It is used in religious ceremonies, such as the chrism used in baptism, and has traditionally been used to anoint kings and queens. Oil that is associated with one or more saints is known as "oil of saints" and believed by some to have beneficial properties, as is "oil of martyrs"[1].

## See also

- Emulsifier, allow oils and water to mix
- Wax, compounds with oil-like properties that are solid at common temperature

## References

1. ^ CATHOLIC ENCYCLOPEDIA: Oil of Saints (http://www.newadvent.org/cathen/11228d.htm)

## External links

- Petroleum Online e-Learning resource from IHRDC (http://www.petroleumonline.com)

# Extract

From Wikipedia, the free encyclopedia

*This article incorporates text from the public domain 1911 edition of The Grocer's Encyclopedia.*

An **extract** is a substance made by extracting a part of a raw material, often by using a solvent such as ethanol or water. Extracts may be sold as tinctures or in powder form.

The aromatic principles of many spices, nuts, herbs, fruits, etc., and some flowers, are marketed as extracts, among the best known of true extracts being almond, cinnamon, cloves, ginger, lemon, nutmeg, orange, peppermint, pistachio, rose, spearmint, vanilla, violet, and wintergreen.

## Extraction techniques

The majority of natural essences are obtained by extracting the essential oil from the blossoms, fruit, roots, etc., or the whole plants, through four techniques:

- Expression when the oil is very plentiful and easily obtained, as in lemon peel.
- Absorption is generally accomplished by steeping in alcohol, as vanilla beans.
- Maceration is used to create smaller bits of the whole, as in making peppermint extract, etc.
- Distillation is used with maceration, but in many cases, it requires expert chemical knowledge and the erection of costly stills.

The distinctive flavors of nearly all fruits, in the popular acceptance of the word, are very desirable adjuncts to many food preparations, but there are only a few from which it is practicable to obtain a concentrated flavor extract of the necessary strength. Among those which lend themselves readily to the manufacture of "pure" extracts the most important are lemons, oranges and vanilla beans.

## Chemical-created essence

A majority of other, concentrated fruit flavors, such as banana, cherry, currant, peach, pineapple, raspberry and strawberry, are produced by combinations of various esters, together with special oils. The desired colors are generally obtained by the use of dyes. Among the esters most generally employed are ethyl acetate and ethyl butyrate. The chief factors in the production of artificial banana and pineapple extract, and also important in the manufacture of strawberry extract, are amyl acetate and amyl butyrate, amyl alcohol being the principal constituent of that part of the alcohol obtained by the distillation of grain and potato starch, which is popularly known in the US as fusel oil and in Europe, generally by the title of potato oil.

Artificial extracts do not, as a rule, possess the delicacy of the fruit flavor, but they get sufficiently close to it to be of real service and convenience when true essences are unobtainable or considered to be too expensive.

## References

Retrieved from "http://en.wikipedia.org/wiki/Extract"
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**Definitions**

**extract**

*noun*

1. That which is extracted or drawn out.
2. A portion of a book or document, separately transcribed; a citation; a quotation.
3. A decoction, solution, or infusion made by drawing out from any substance that which gives it its essential and characteristic virtue; essence; as, extract of beef; extract of dandelion; also, any substance so extracted, and characteristic of that from which it is obtained; as, quinine is the most important extract of Peruvian bark.
4. A solid preparation obtained by evaporating a solution of a drug, etc., or the fresh juice of a plant; -- distinguished from an abstract.
5. A peculiar principle once erroneously supposed to form the basis of all vegetable extracts; -- called also the extractive principle.
6. Extraction; descent.
7. A draught or copy of writing; certified copy of the proceedings in an action and the judgement therein, with an order for execution.

***Translations:***

*verb*

1. (*transitive*) To draw out or forth; to pull out; to remove forcibly from a fixed position, as by traction or suction, etc.; as, to extract a tooth from its socket, a stump from the earth, a splinter from the finger.
2. (*transitive*) To withdraw by expression, distillation, or other mechanical or chemical process; as, to extract an essence. Cf. Abstract, v. t., 6.
3. (*transitive*) To take by selection; to choose out; to cite or quote, as a passage from a book.
4. (*context, transitive, arithmetic*) To determine (a root of a number).

   *Please the third root of 27.*

***Translations:***

- French: extraire (*trans-mid*)
- Italian: cavare (*trans-bottom*) (*trans-top, to withdraw in process*)

***Etymology:***

- From Latin *extractum*, past participle of *extrahere*.

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**Definitions**

**oil**

*noun*

1. liquid, Liquid fat.
2. petroleum, Petroleum-based liquid used as fuel or lubricant.

*verb*

1. (*transitive*) to lubricate with oil
2. (*transitive*) to grease with oil for cooking

Full Definition of oil



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